DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 8 1999

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Robert S. Milanese
President
National Association of
Pharmaceutical Manufacturers
320 Old Country Road
Garden City, New York 11530-1752

Re: Docket No. 99P-1658/CP1

Dear Mr. Milanese:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on May 27, 1999. Your petition requests that FDA amend its regulations at 21 CFR 314.92 and 320.1 by codifying the Agency's existing practice of applying scientific judgment in determining whether the active ingredients in two drug products are the "same as" or "identical to" each other for purposes of deciding whether an abbreviated new drug application may be submitted for a particular drug product.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-1658

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